

The background is a dark blue gradient with several large, concentric circles in lighter shades of blue. A faint, stylized image of a coronavirus particle is visible in the center. The Novavax logo is prominently displayed in white, bold, sans-serif capital letters.

NOVAVAX

Creating Tomorrow's Vaccines Today

NVX-CoV2373 Vaccine Candidate

ACIP | October 30, 2020

Filip Dubovsky MD MPH, Chief Medical Officer

Safe Harbor Statement

Certain information, particularly information relating to future performance and other business matters, including expectations regarding clinical development, market opportunities and anticipated milestones constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act.

Forward-looking statements may generally contain words such as “believe,” “may,” “could,” “will,” “possible,” “can,” “estimate,” “continue,” “ongoing,” “consider,” “intend,” “indicate,” “plan,” “project,” “expect,” “should,” “would,” or “assume” or variations of such words or other words with similar meanings. Novavax cautions that these forward-looking statements are subject to numerous assumptions, risks and uncertainties that change over time and may cause actual results to differ materially from the results discussed in the forward-looking statements.

Uncertainties include but are not limited to clinical trial results, dependence on third party contractors, competition for clinical resources and patient enrollment and risks that we may lack the financial resources to fund ongoing operations.

Additional information on Risk Factors are contained in Novavax’ filings with the U.S. Securities and Exchange Commission, including our Annual Report on Form 10-K for the year ended December 31, 2019, our Quarterly Reports on Form 10-Q, and our Current Reports on Form 8-K, which are all available at <http://www.sec.gov>.

Forward-looking statements are based on current expectations and assumptions and currently available data and are neither predictions nor guarantees of future events or performance.

Current results may not be predictive of future results.

You should not place undue reliance on forward-looking statements which speak only as of the date hereof.

The Company does not undertake to update or revise any forward-looking statements after they are made, whether as a result of new information, future events, or otherwise, except as required by applicable law.

Matrix-M and NanoFlu are trademarks of Novavax, Inc.

Outline

- Vaccine Design
- Non-human primate protection study
- Phase 1
 - Day 35 safety and immunogenicity data
- Phase 2
 - Dose 1 and Dose 2 reactogenicity data
- Phase 3 Outline

NVX-CoV2373 Vaccine Design

Vaccine Platform Technology: Nanoparticle vaccine formulated with Matrix-M1

Antigen expressed in baculovirus-*S. frugiperda* system

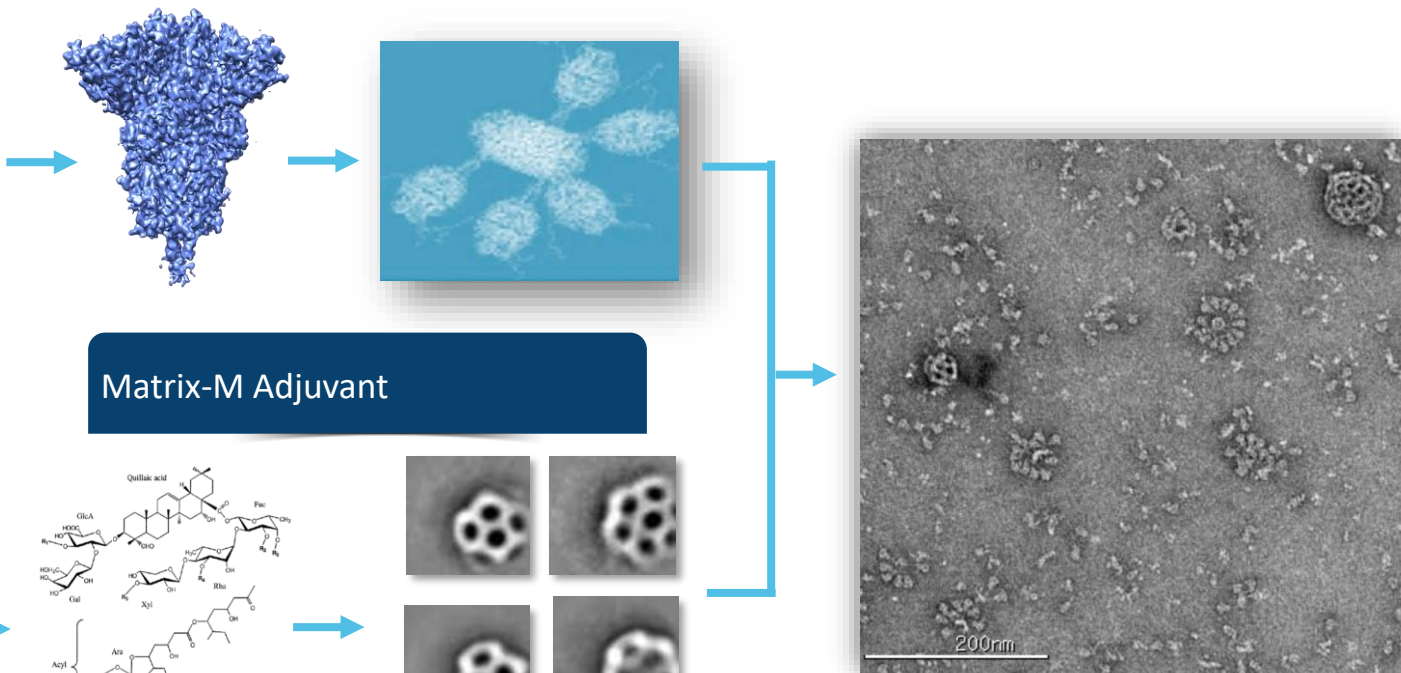
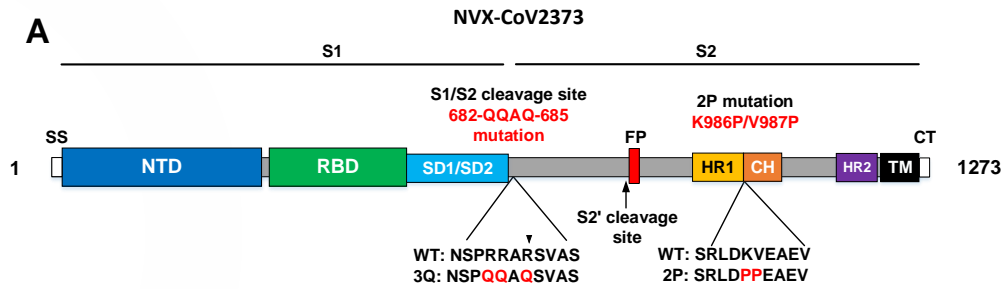
- Codon-optimized
- Full-length protein, including transmembrane domain
- Furin cleavage site mutated and stabilized

Drug Substance

- Native conformation trimers
- Stable PS80 nanoparticle

Drug Product

- Co-formulated with adjuvant
- Dispensed in vial
- Stored 2-8°C

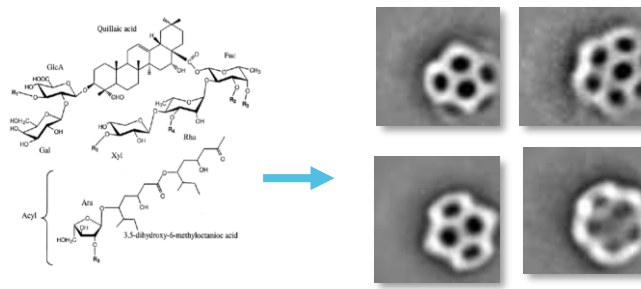


Matrix-M adjuvant

- Purified from *Quillaja saponaria molina*



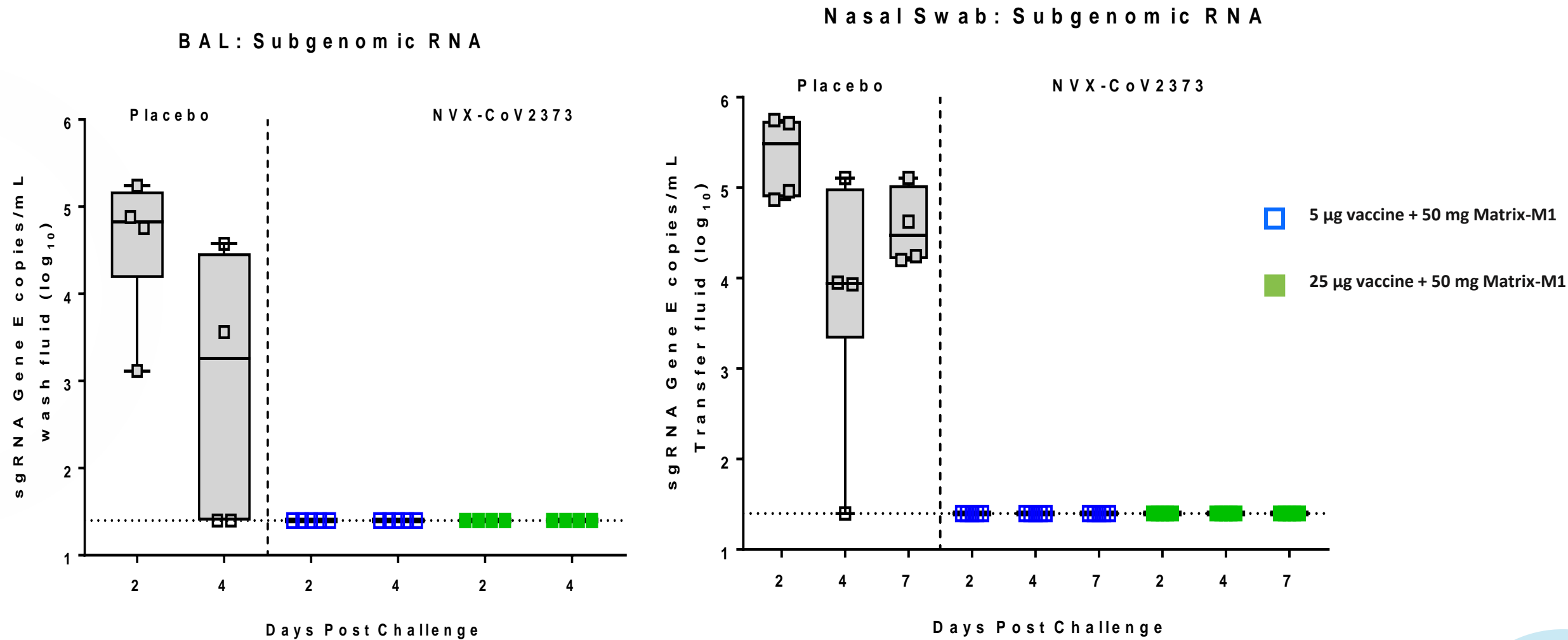
Matrix-M Adjuvant



Rhesus Macaques: Upper and Lower airway protection

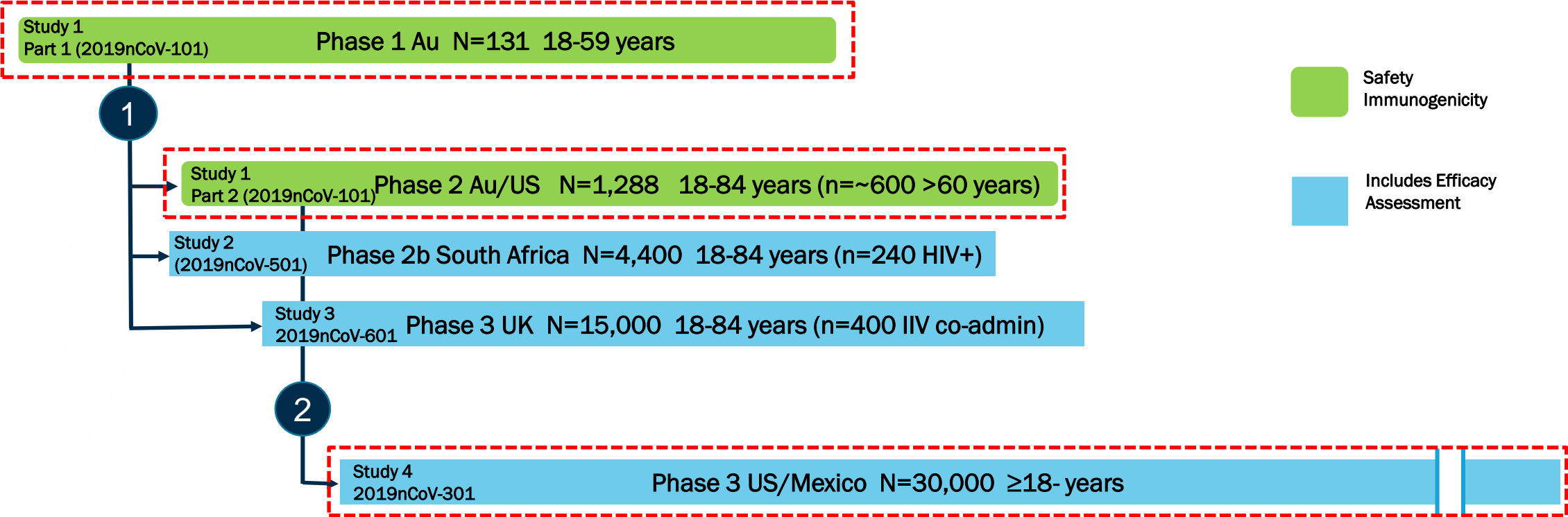
Vaccinated Day 0 and Day 21; Challenged with SARS-CoV-2 wild-type 1.05×10^6 PFU IN/IT on Day 38
No viral replication detected in upper or lower airway following experimental wild-type challenge

Partner: OWS
Sponsor: Novavax



Pre-publication data: study conducted at Texas Biomedical Research Institute

NVX-CoV2373 High Level Clinical Development Plan



1

Dose confirmation based on Phase 1 data Aug 2020

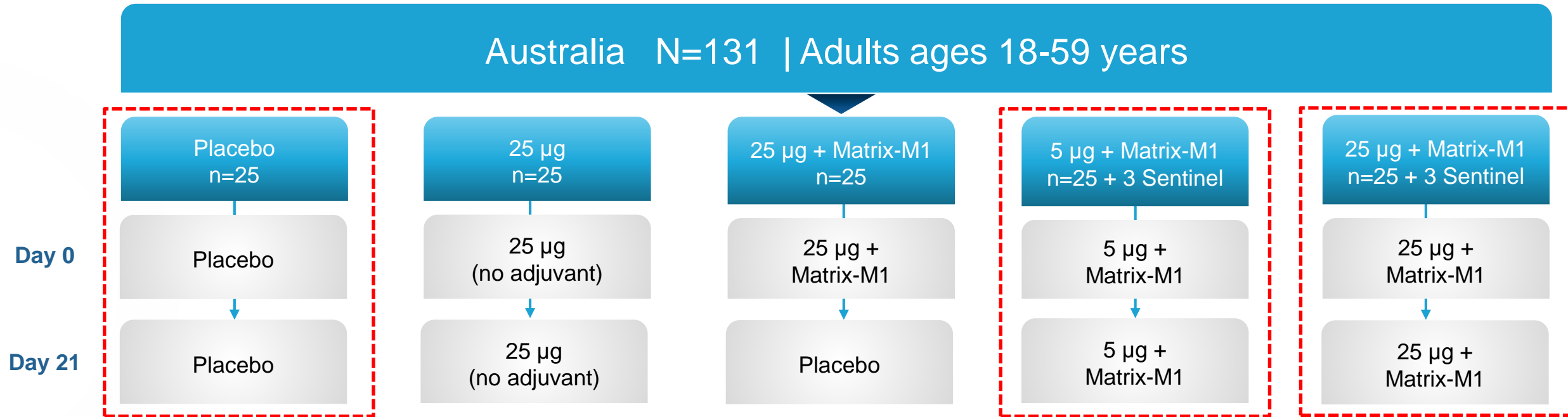
2

Dose confirmation in adults >60 y based on Phase 2: Oct 2020

Phase 1 Design and Status

First-in-Human Safety and Immunogenicity

Partner: CEPI
Sponsor: Novavax



- Study is fully enrolled, and safety and immunogenicity follow-up is ongoing
- Study sites, investigators, CRO and participants are blinded to individual vaccine/placebo allocation
- Day 35 (14 days after Dose 2) safety and immunogenicity data reviewed by SMC & FDA in advance of Phase 2 study

Keech et al. NEJM 02 September 2020

Day 35 Safety Summary

Consistent with previous nanoparticle vaccine with Matrix-M1

Partner: CEPI
Sponsor: Novavax

- No Serious Adverse Events
- Adverse events of Special Interest
 - No Potentially Immune-Mediated Medical Condition AESIs
 - No Confirmed COVID-19 AESIs
- Treatment Emergent Adverse Events
 - All mild and moderate and balanced in active arms (no severe events)
- Reactogenicity Symptoms
 - Majority of subjects reported “none” or “mild”
 - Mean duration <2 days for both Local and Systemic Reactogenicity Symptoms

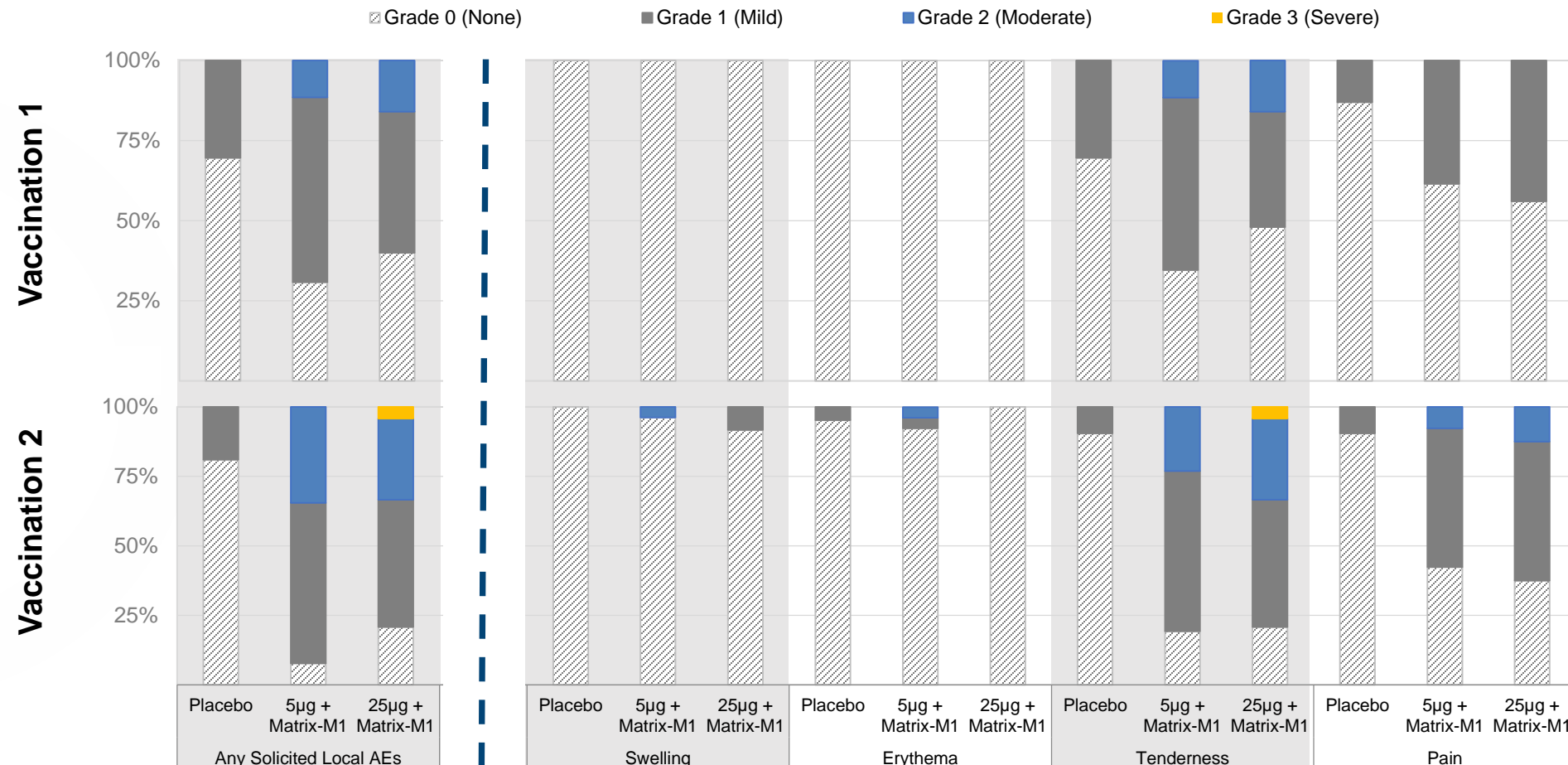
Keech et al. NEJM 02 September 2020

Local Reactogenicity Symptoms collected 7 days after each dose

2 Dose vaccine groups compared to placebo

Majority of Symptoms Grade 0 or Grade 1

Partner: CEPI
Sponsor: Novavax



- Local symptoms increased after Dose 2
- Increased rate and severity in Matrix-M1 groups
- Pain and Tenderness were reported most commonly
- Mean duration < 2 days

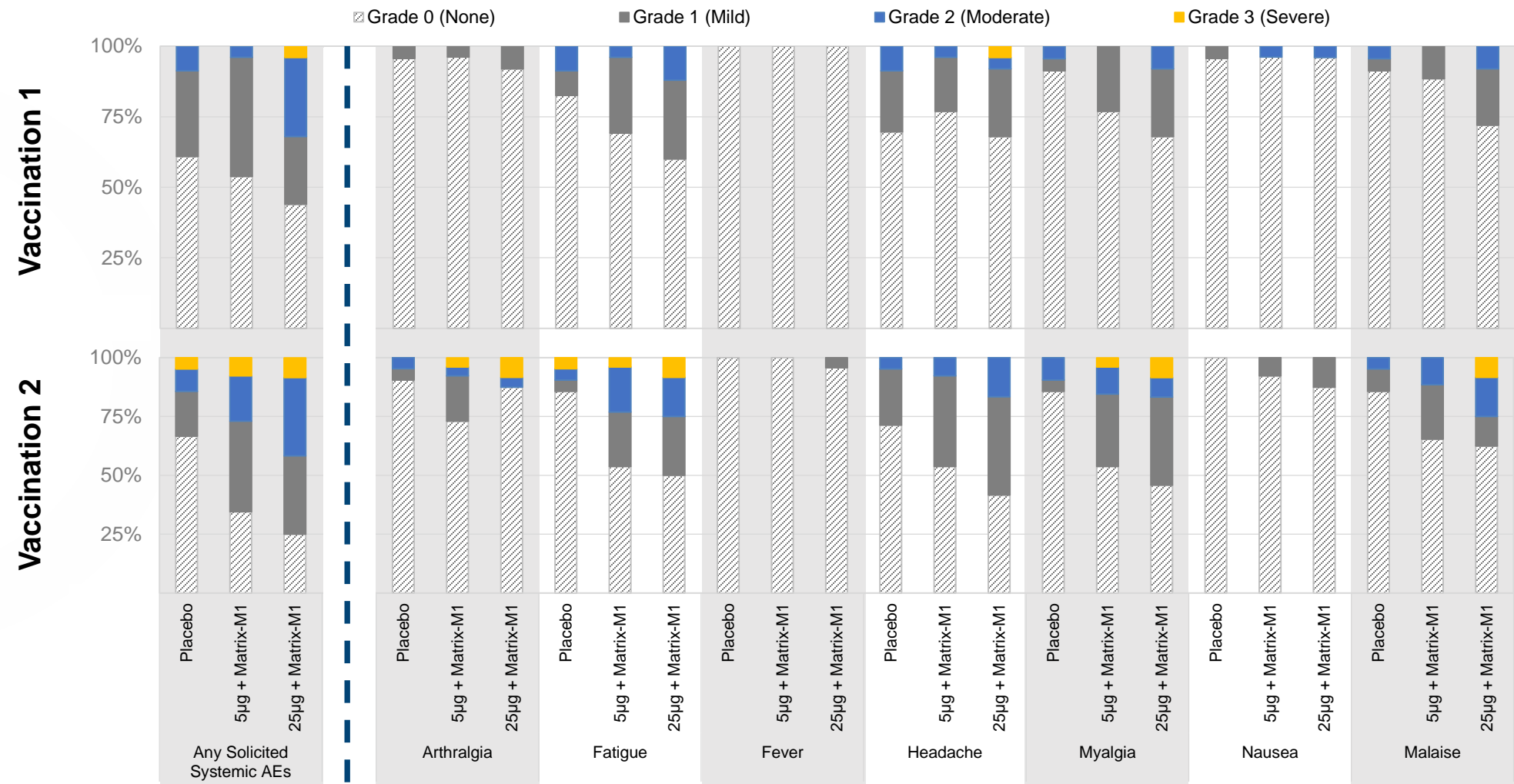
Keech et al. NEJM 02 September 2020

Systemic Reactogenicity Symptoms collected 7 days after each dose

2 Dose adjuvanted vaccine groups compared to placebo

Majority of Symptoms Grade 0 or Grade 1

Partner: CEPI
Sponsor: Novavax



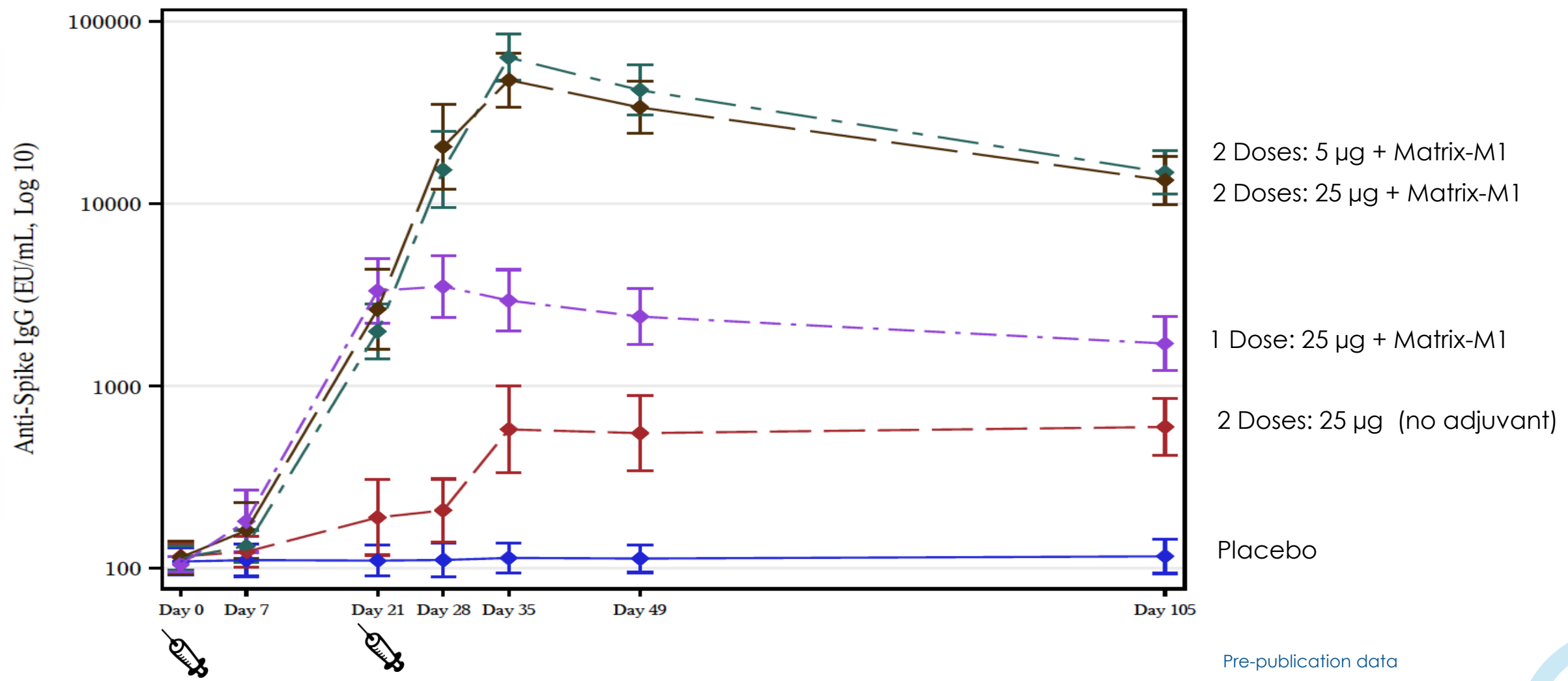
- Systemic Symptoms increased after Dose 2
- Increased rate and severity in Matrix-M1 groups
- Headache, Fatigue and Myalgia were reported most commonly
- Mean duration < 2 days

Keech et al. NEJM 02 September 2020

Anti-Spike IgG ELISA Kinetics

Vaccination on Day 0 and D21; Peak immune response on Day 35 in 2 dose schedule
Matrix-M1 required for optimal immune response; 2 doses adjuvanted vaccine superior to 1 dose
Martix-M1 is dose-sparing with 5ug + Matrix-M1 comparable to 25ug + Matrix-M1

Partner: CEPI
Sponsor: Novavax

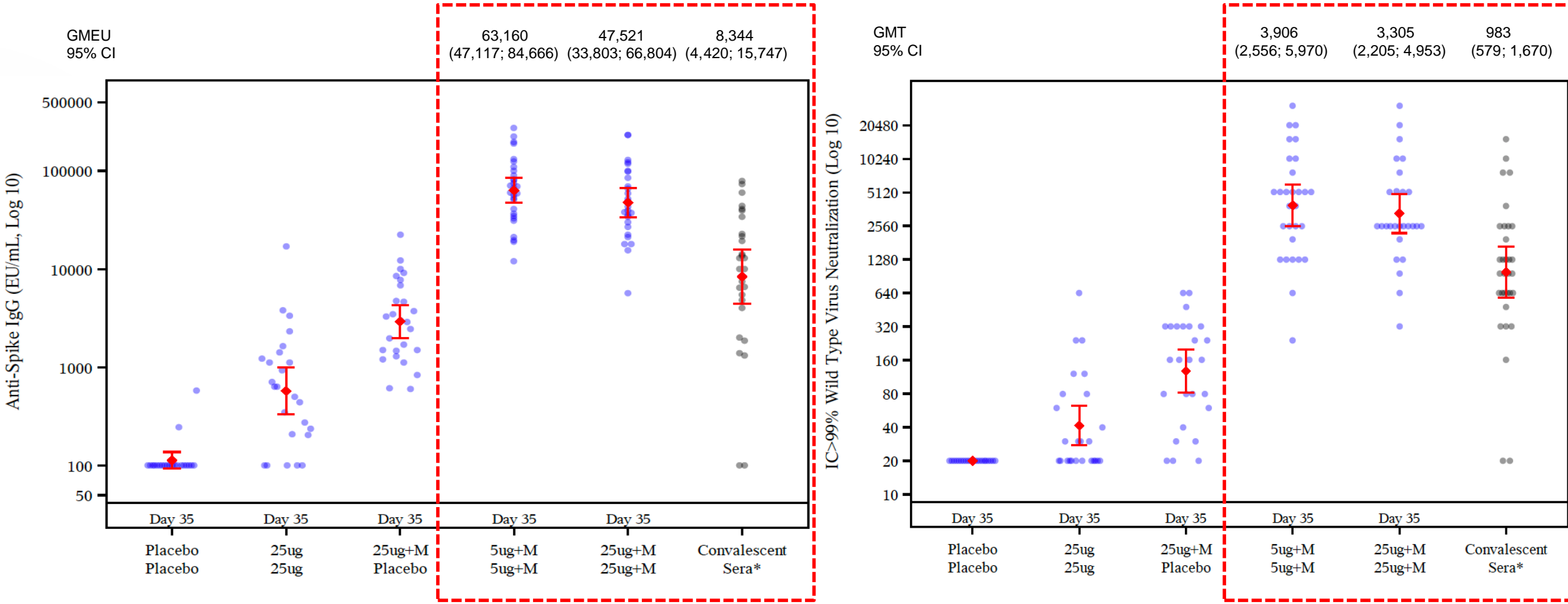


Pre-publication data

Day 35 anti-S IgG ELISA and 100% wild-type neutralization responses

Robust IgG and neutralization response induced after 2 doses of adjuvanted vaccine
100% IgG and neutralization seroconversion achieved after 2 doses of adjuvanted vaccine

Partner: CEPI
Sponsor: Novavax



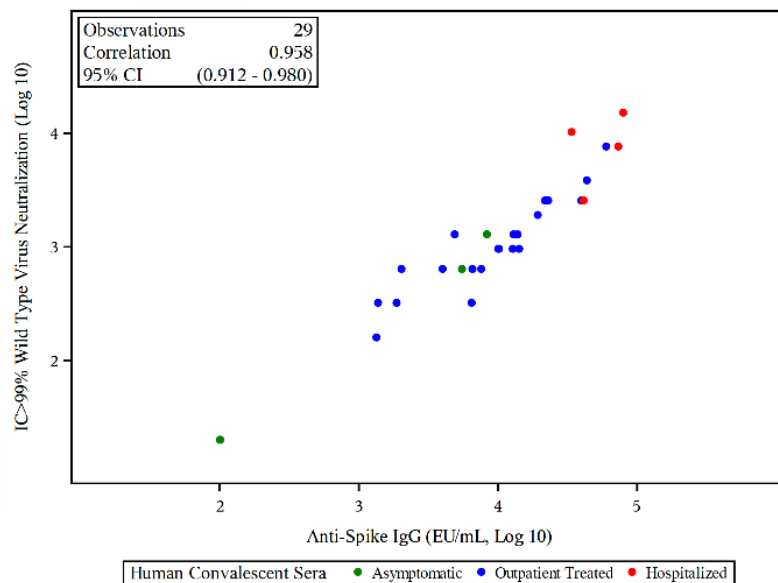
*Convalescent Sera donated by Dr Pedro A Piedra Baylor College of Medicine (samples obtained median 19 days after diagnosis, 10% asymptomatic, 77% outpatient ER, 13% hospitalized)
Wild-type neutralization assay conducted by the Dr Matthew Frieman Lab University of Maryland School of Medicine

Scatter plot of IgG vs 100% wild-type neutralization

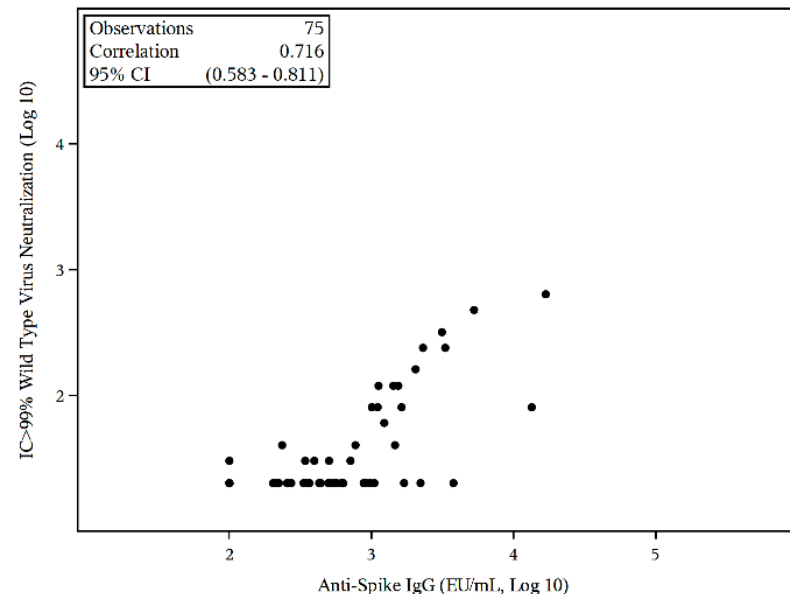
Adjuvanted vaccine induces IgG response that correlates tightly with neutralization response
Significant and consistent proportion of antibody is functional

Partner: CEPI
Sponsor: Novavax

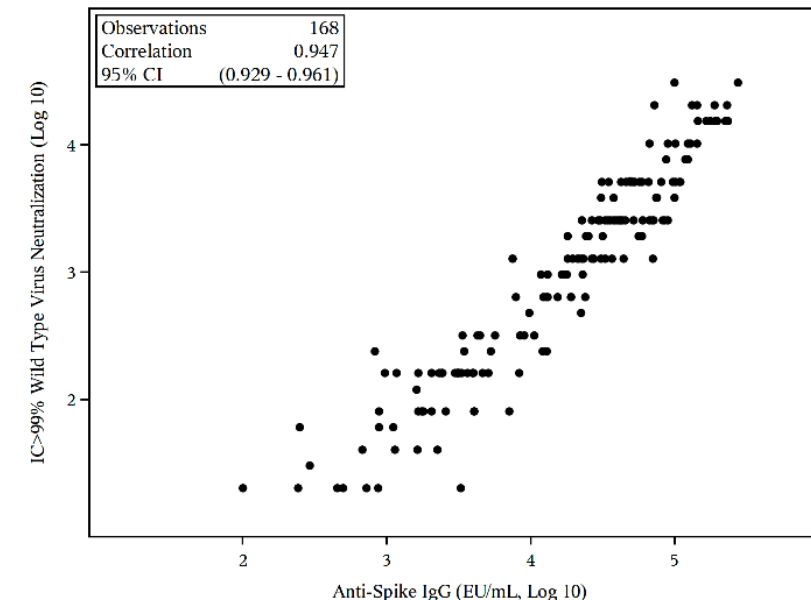
Baylor Convalescent Serum*



2 Dose: 25 µg (no adjuvant)



2 Dose 5 µg + Matrix-M1
combined with
2 Dose 25 µg + Matrix-M1



*Convalescent Sera donated by Dr Pedro A Piedra Baylor College of Medicine (samples obtained median 19 days after diagnosis, 10% asymptomatic, 77% outpatient ER, 13% hospitalized)
Wild-type neutralization assay conducted by the Dr Matthew Frieman Lab University of Maryland School of Medicine

Keech et al. NEJM 02 September 2020

Intracellular Cytokine Staining Ag-Specific CD4 T cells Analysis

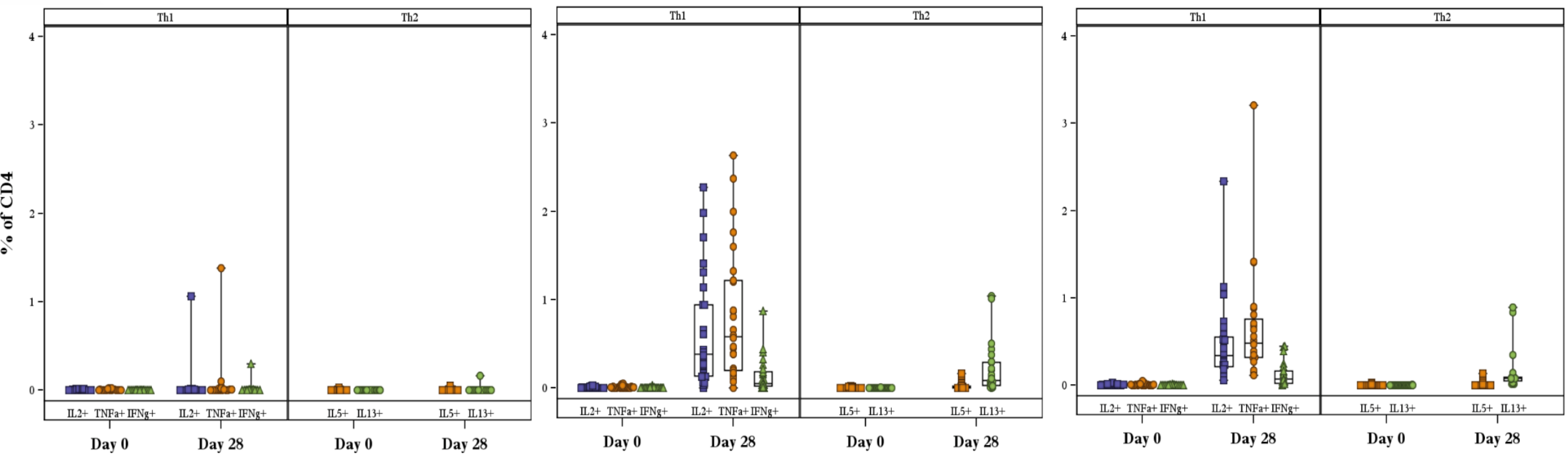
Matrix-M1 induced Th1 biased immune response as predicted by non-clinical data

Partner: CEPI
Sponsor: Novavax

Placebo

2 Doses: 5 µg + Matrix-M

2 Doses: 25 µg + Matrix-M



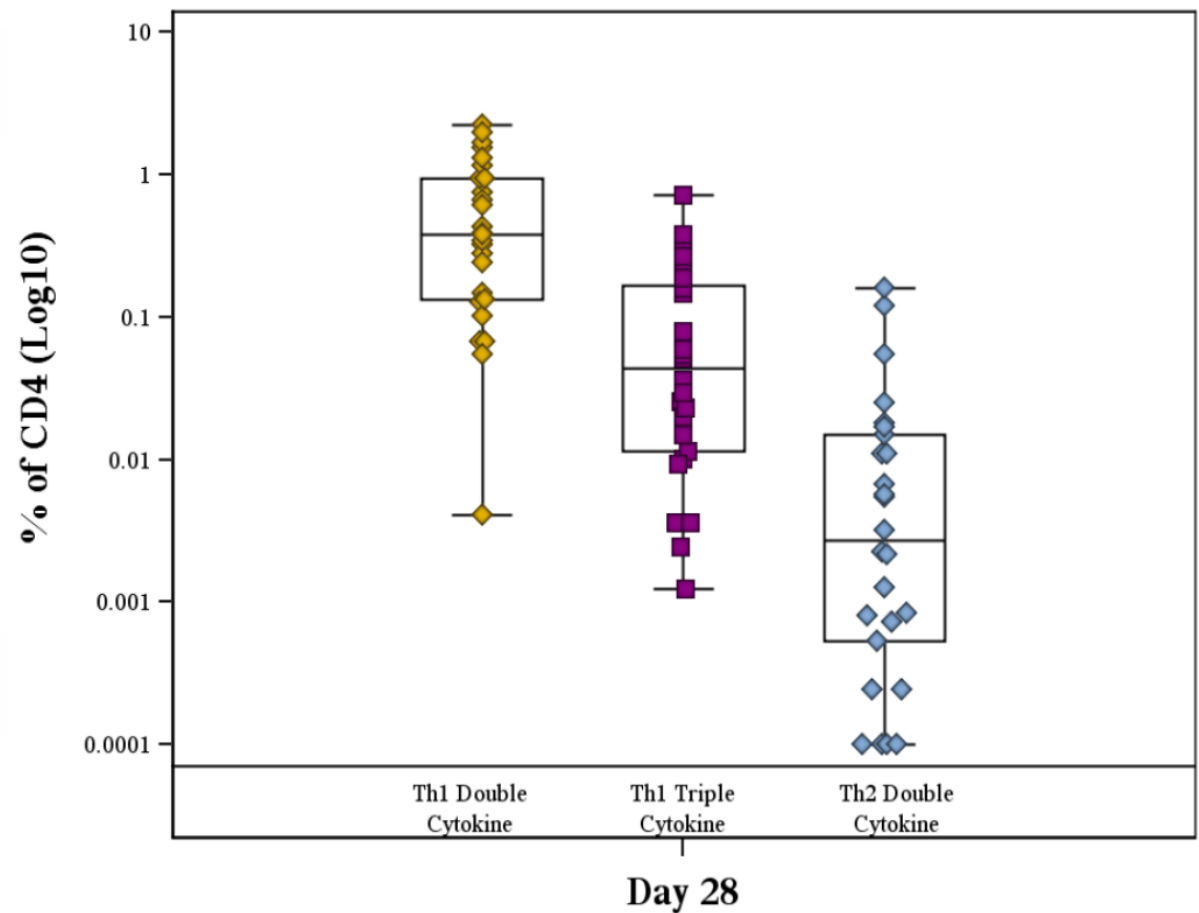
Pre-publication data

Intracellular Cytokine Staining Ag-Specific CD4 T cells Analysis (CD45+, CCR7-)

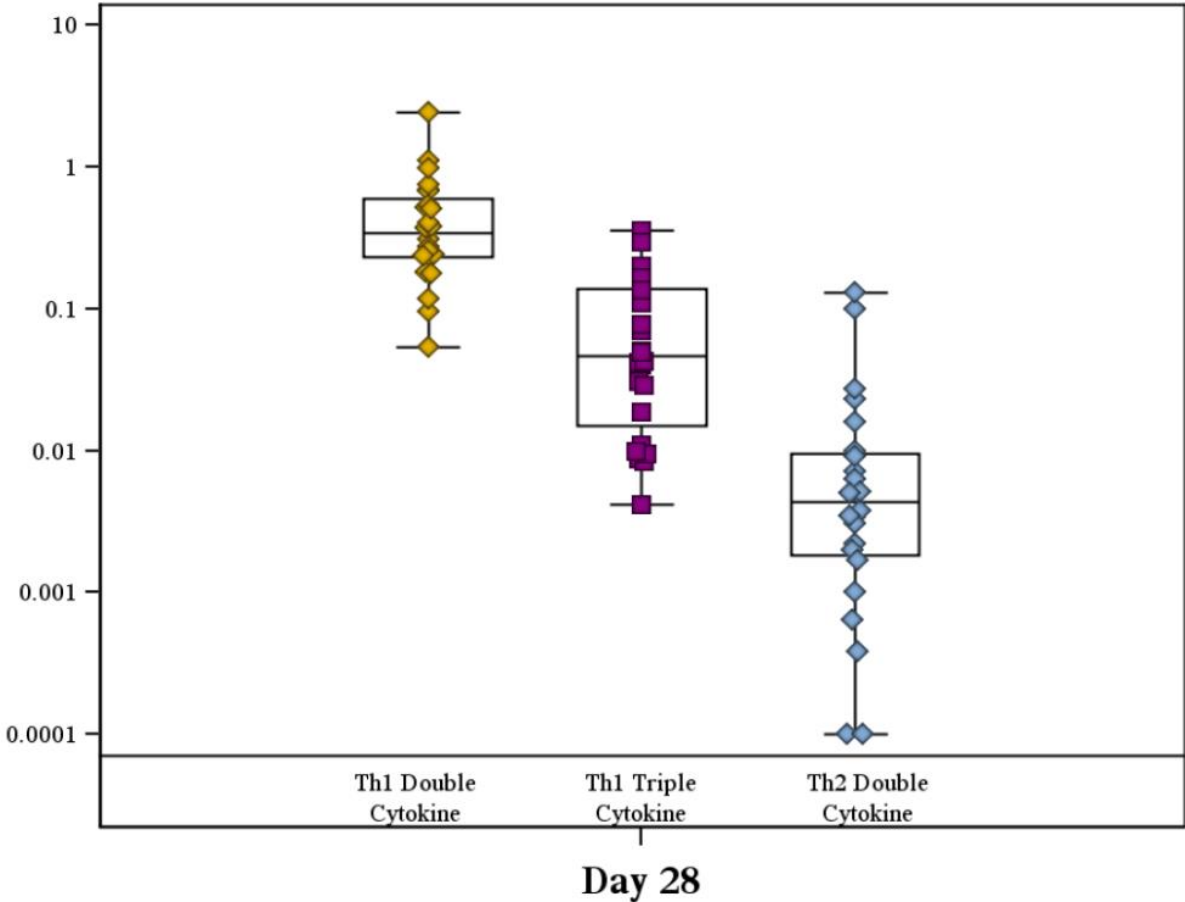
Double and triple Th1 cytokine response compared to double Th2 cytokine response

Partner: CEPI
Sponsor: Novavax

2 Doses: 5 µg + Matrix-M



2 Doses: 25 µg + Matrix-M



Pre-publication data

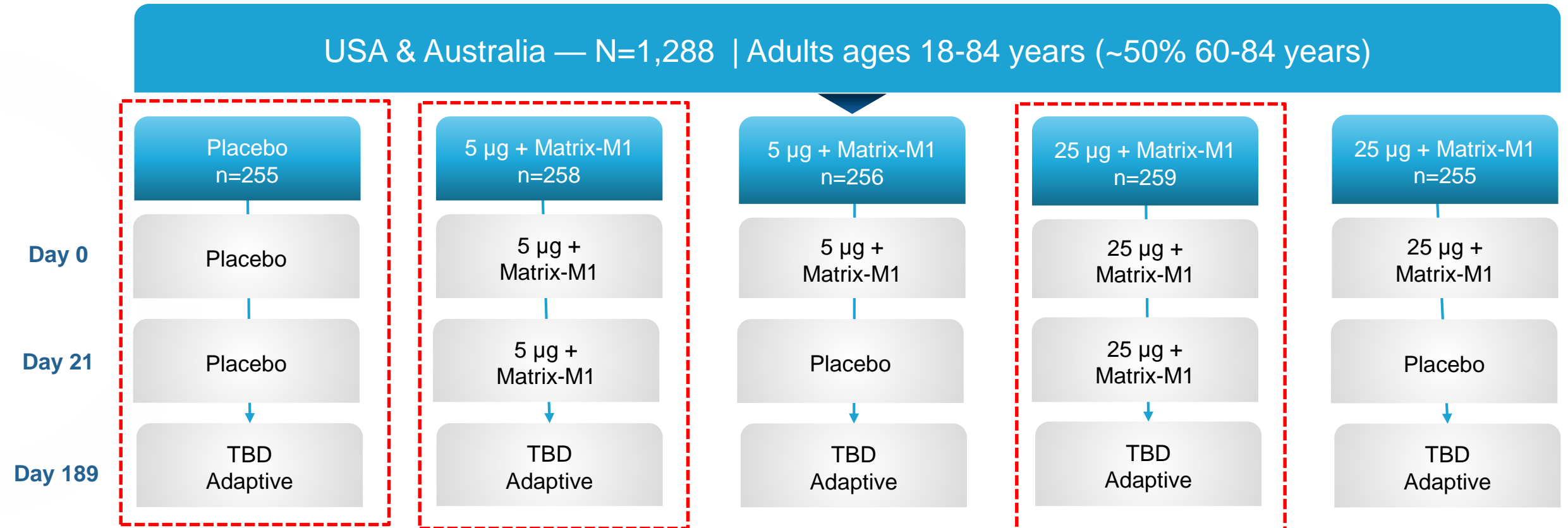
Novavax Phase 1 Study Conclusions

- Reactogenicity and safety profiles are reassuring for both 5 µg and 25 µg dose groups when formulated with Matrix-M1 adjuvant
- Immunogenicity Conclusions
 - Matrix-M1 adjuvant is required to induce an optimal functional immune response
 - Two doses of vaccine administered 21 days apart are superior to a single dose
 - 5 µg and 25 µg induce comparable immune responses when formulated with Matrix-M1
 - Matrix-M1 induces a Th1 biased immune response with high levels of neutralizing antibody
- The safety and immunogenicity profile of both 5 µg and 25 µg formulated with Matrix-M1 and administered on Day 0, 21 is acceptable for further clinical evaluation

Phase 2 design and status

Expanded safety and dose confirmation

Partner: CEPI
Sponsor: Novavax



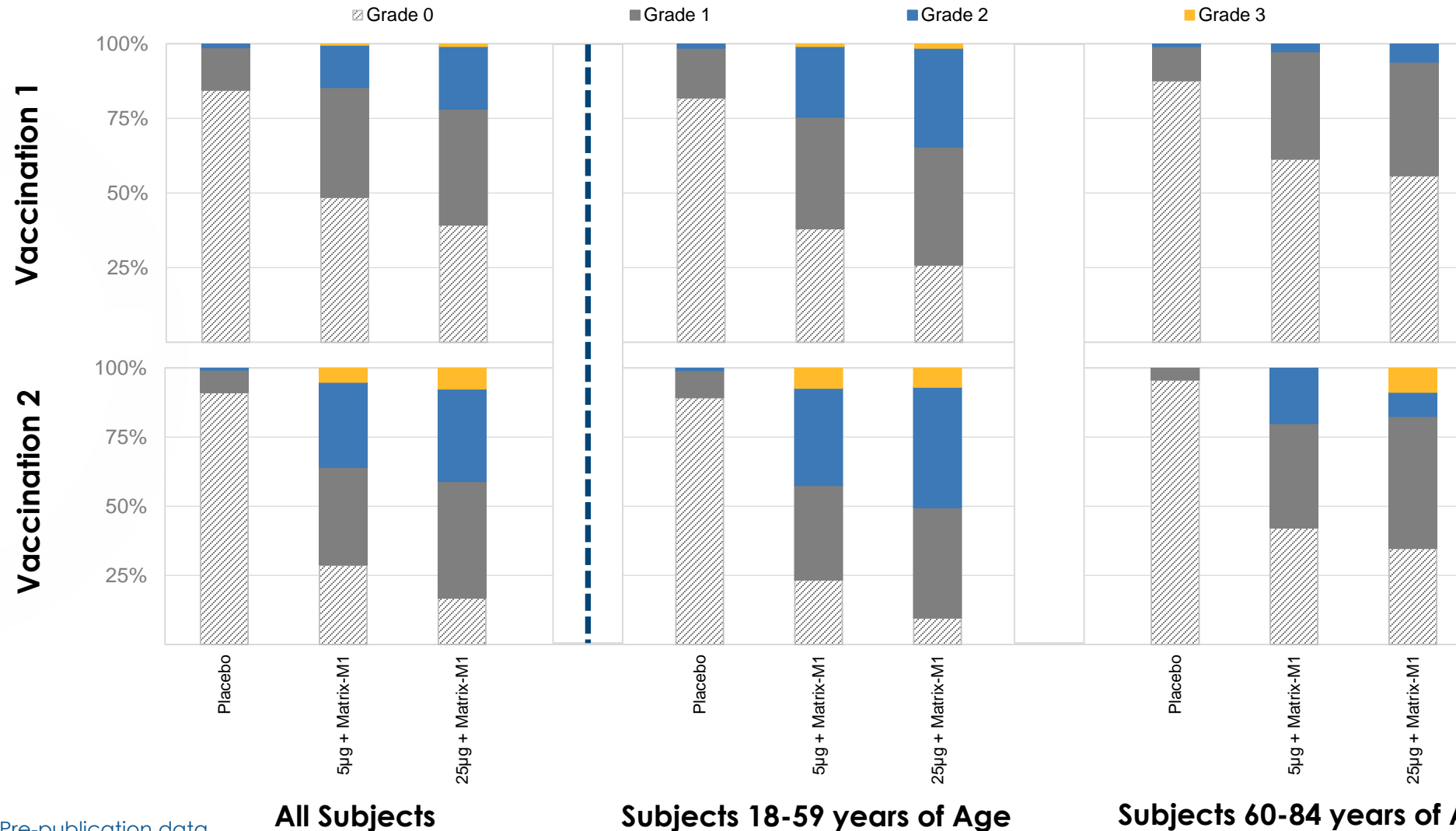
- Study is fully enrolled, Dose 2 has been administered, and safety and immunogenicity follow-up is ongoing
- Study sites, investigators, CRO and participants are blinded to individual vaccine/placebo allocation
- Reactogenicity data reviewed by SMC & FDA in advance of Phase 3 study

Local Reactogenicity Events in 2 Dose adjuvanted groups

2 Dose adjuvanted groups compared to placebo

Worst grade reported for 7 days after each dose: raw blinded data Oct 5 cut-off

Partner: CEPI
Sponsor: Novavax



- Pain and Tenderness reported most frequently
- Increased rates seen in adjuvanted groups especially after Dose 2
- Reactogenicity attenuated in adults >60 years of age
- Terms include:
 - Pain
 - Tenderness
 - Erythema
 - Swelling

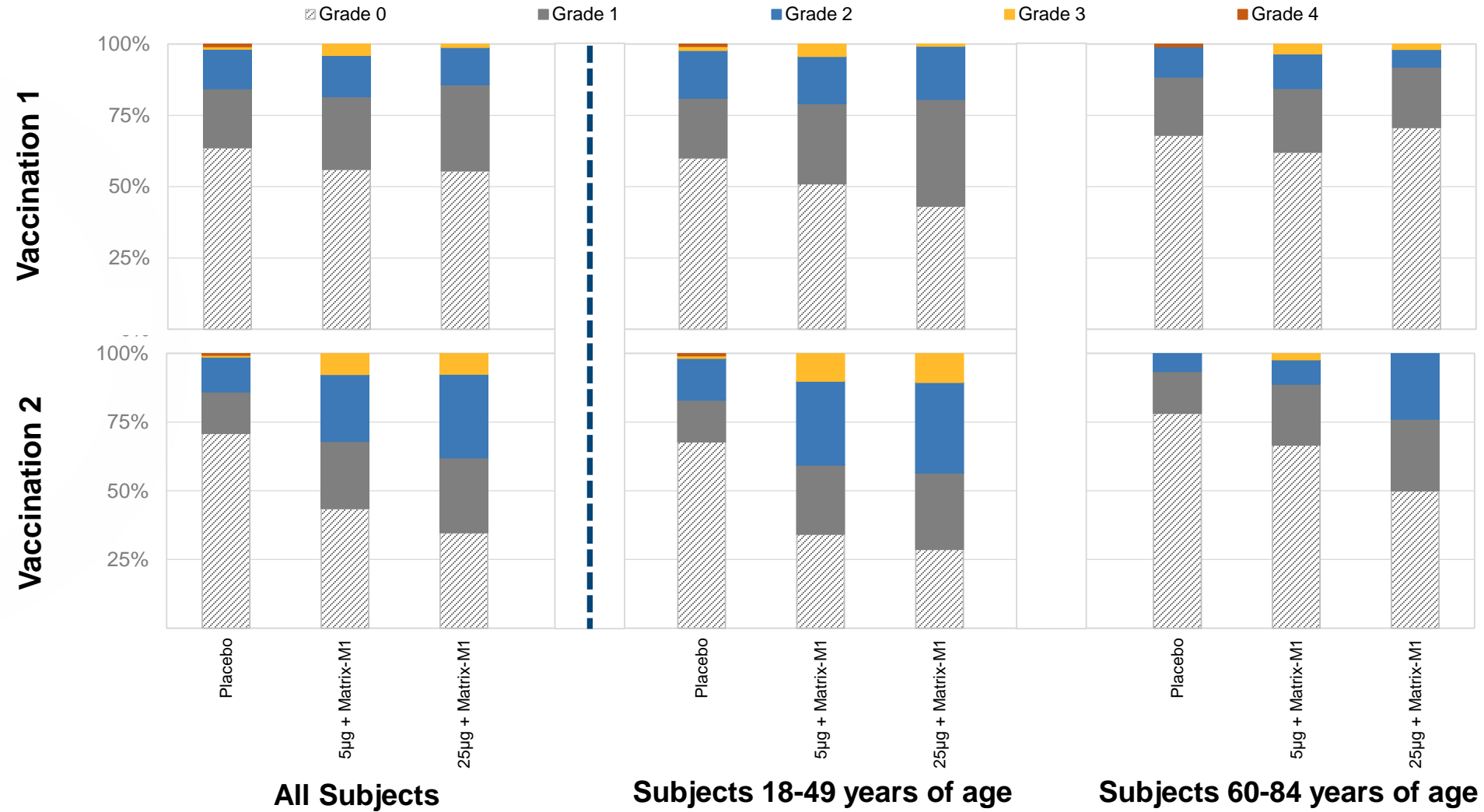
Pre-publication data

Systemic Reactogenicity Events in 2 Dose adjuvanted groups

2 Dose adjuvanted groups compared to placebo

Worst grade reported for 7 days after each dose: raw blinded data Oct 5 cut-off

Partner: CEPI
Sponsor: Novavax



- Fatigue, Headache and Myalgia reported most frequently
- Increased rates seen in adjuvanted groups especially after Dose 2
- Reactogenicity attenuated in adults >60 years of age
- Terms include:
 - Arthralgia
 - Fatigue
 - Fever
 - Headache
 - Myalgia
 - Nausea
 - Malaise

Pre-publication data

US/Mexico Phase 3 Design and Status

Pivotal Safety and Efficacy

Partner: OWS/CoVPN
Sponsor: Novavax

- Phase 3, randomized, observer-blinded, placebo-controlled study
- Randomized 2:1 to receive 5 µg + Matrix-M1 vaccine or Placebo
- 2 doses 0.5ml administered on Day 0 and Day 21
- Up to 30,000 adults >18 years of age across USA and Mexico
 - Target at least 25% ≥ 65 years of age
 - Target at least 25% with high-risk co-morbidities
 - Target at least 15% black/African Americans, 10-20% LatinX, 1-2% Native Americans
- Endpoint driven study with efficacy evaluations at 72, 108 and 144 cases
- Primary Endpoint: Prevention of PCR-confirmed mild, moderate, or severe COVID-19 illness occurring 7 days after Dose 2 in baseline seronegative adults
- Safety follow-up through 2 years

NVX-CoV2373 Summary

- Vaccine based on the baculovirus/nanoparticle platform technology
 - Safety database includes >12,100 nanoparticle vaccinees (RSV, influenza, Ebola)
 - Safety database includes >2,500 nanoparticle vaccinees adjuvanted with Matrix-M1
- Ten-dose vials with transportation and storage at 2-8° C
- Preservative-free; no admixing or reconstitution required
- 0.5 ml administered intramuscularly 21 days apart
- Preliminary safety profile reassuring with favorable reactogenicity profile
- Peak immune response 14 days after dose 2
- Favorable immunologic phenotype
 - Robust neutralizing antibody response
 - Polyfunctional CD4+ Th1 biased cellular immune response
- Efficacy evaluation ongoing